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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/300,482	04/28/1999	NORDINE CHEIKH	04983.0031.U	4511

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EXAMINER	
MORAN, MARJORIE A	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/300,482	CHEIKH ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/16/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-13,15-22,24,28 and 30-39* is/are pending in the application.

4a) Of the above claim(s) *32-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-13,15-22,24,28,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper.No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Claims 32-39 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention designated as Group IV (transgenic plants) in the restriction requirement mailed 9/20/2000, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed as Paper No. 7 on 10/6/2000.

This application contains claims 32-39 drawn to an invention nonelected with traverse in the reply filed 10/6/2000. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 11-13, 15-22, 24, 28, and 30-39 are pending. An office action on the merits of elected claims 1, 11-13, 15-22, 24, 28, and 30-31 follows.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 11-13, 15-22, 24, 28 and 30-31 are again rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.
The arguments filed 10/16/06 have been fully considered but are not persuasive.

Applicant's statement that some of the claims do not recite enzymes is recognized. In response, it is again noted that the claims are directed to nucleic acids. To clarify, a nucleic

acid which is a promoter or other regulatory element has a well-established utility. A polynucleotide sequence which is known to comprise a particular mutation or is known to be expressed only in a particular tissue, such that the nucleic acid, itself, has a specific, substantial and credible utility (e.g. for identifying a tissue or disease associated with the mutation) has utility. The instant nucleic acids do not have a known or recognized utility for these or similar reasons, as previously set forth. As set forth in previous office actions, where a nucleic acid does not, in itself, have a utility, utility maybe established based on a polypeptide encoded; i.e. if the polypeptide has utility, then the encoding nucleic acid has an "associated" utility BASED ON THE KNOWN OR ESTABLISHED UTILITY OF THE POLYPEPTIDE. In the instant case, as none of the claimed nucleic acids have a well established or specific, substantial and credible utility in themselves, utility was examined *based on the disclosure* (i.e. as asserted utility) that all the claimed nucleic acids encode enzymes.

In response to the argument that the there must be "sound scientific reasoning" or evidence to rebut the assertion that the claimed sequences encode phosphogluconate pathway enzymes, it is again noted and maintained that the specification does not actually disclose that any of the claimed SEQ ID NO's is known to encode a protein or peptide, specifically one of the enzymes recited in the claims. For the nucleic acid to have utility based on a putatively encoded peptide, the identity and activity of the peptide must be known or established. With regard to the arguments that the examiner "admits that Table A indicates "Identity" with known proteins, it is again noted that Table A discloses only that SEQ ID NO: 1, for example, is PREDICTED to encode a polypeptide with 58% homology to a dehydrogenase. There is no teaching that conserved domains specific to dehydrogenases are encoded, etc. such that one skilled in the art would conclude that the claimed sequence does indeed encode a dehydrogenase. Similarly, there is no evidence anywhere with regard to actual activity,

conserved domains, catalytic domains encoded, etc. for the instantly claimed sequences that would lead one skilled in the art to conclude that the claimed sequences do indeed encode peptides or proteins with any activity, specifically that of the enzymes argued by applicants and recited in the claims. Thus, in the absence of further experimentation, *and using sound scientific reasoning*, one skilled in the art would not be able to ascertain with any degree of certainty whether the claimed nucleic acids do, in fact encode the claimed or asserted enzymes.

For all the reasons previously set forth and set forth above, the rejection is maintained.

Claims 1, 11-13, 15-22, 24, 28 and 30-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. As the utility rejection is maintained, so is the enablement rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 22, 24 and 28 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

Applicant's arguments filed 4/24/06 have been fully considered, but are not persuasive. In response to the argument that one skilled in the art would know how to use the claimed nucleic acids to encode an enzyme, it is again noted that the instant specification does not disclose any comparison of conserved regions, catalytic domains, etc., between known enzymes and putatively encoded peptides such that one skilled in the art would be able to determine whether the instantly claimed polynucleotides actually encode polypeptides with enzymatic activity. While it is admitted that routine and well-known steps do not constitute "undue experimentation," it is noted that in the instant case, one skilled in the art must guess at a reading frame for translation, must determine an appropriate expression format (cells? what type? cell-free?), must generate an expression vector or cassette with an appropriate promoter, etc., must determine the appropriate conditions for expression, including those required for post-translational processing (and must determine whether such processing is necessary), must guess at appropriate isolation procedures, and must determine how to do all of the above without losing putative enzymatic ability (e.g. many expression systems can, but do not always result in N-terminal blockage, and thus, no activity of the expressed protein). After an assumed peptide is expressed and isolated, presumably under conditions which do not result in loss of activity, one skilled in the art must then determine conditions under which to test for the claimed activity, and must know what particular conditions of salt, temperature, co-factors are required for the particular enzymatic activity being assayed. The examiner maintains that the totality of guesswork and experimentation required to determine whether any of the claimed nucleic acids does indeed encode a peptide with enzymatic activity constitutes undue experimentation.

In response to the repeated argument that the specification sets forth a "detailed description of ...amino acid sequences," it is again noted that the originally filed disclosure, including the specification and Figures, does not disclose any amino acid sequences anywhere.

In response to the argument that the specification describes methods of use of enzymes, it is noted that the rejection is not over whether one skilled in the art would know how to use an enzyme. Given a protein with known enzymatic identity, one of skill in the art would indeed know what "to do" with the protein. The instant rejection is based on the issue that one does not, in fact, know whether the claimed nucleic acids actually encode enzymes, thus one skilled in the art would not know what to do with the NUCLEIC ACIDS. For these reasons and those previously set forth, the examiner maintains that one of skill in the art would not know how "to use" the claimed nucleic acids to encode an enzyme, as claimed.

35 U.S.C. 112, Written Description Rejection

Claims 1, 22, 24, and 28 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619. which putatively encode various phosphogluconate pathway enzymes. Claims 1, 22, 24 and 28 are specifically directed to encompass sequences that encode a variety of enzymes. As the sequences recited in the claims are apparently fragments which do not appear to comprise ORF's or actually encode any known proteins, a nucleic acid "comprising" the fragments encompasses much larger sequences which may encode entirely different proteins with entirely different activities from those of the recited enzymes.

Applicant argues the disclosure need only show that applicant was in possession of the claimed inventions, and insists that the instant specification does so. In response, it is noted that the specification does not, in fact, actually describe any nucleic acid KNOWN to encode an

entire enzyme, and therefore does not describe nor show possession of the claimed invention of at least claims 1, 22, 24, and 28.

For all of the reasons set forth above and previously set forth, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
12/26/06